K121055 (1/2)

SECTION 5:
510(k) SUMMARY

SEP 17 2012

Preparation Date: September 10, 2012

Trade Name: METS® MODULAR TOTAL FEMUR

Common Name: Prosthesis, Hip, Semi-Constrained, Metal/Polymer, Cemented

Classification Name: Hip joint metal/polymer semi-constrained cemented prosthesis (21 CFR 888.3350, Product Code JDI) Knee joint femorotibial metal/polymer constrained cemented prosthesis (21 CFR 888.3510, Product Code KRO)

Applicant/Sponsor:
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210 Centennial Avenue
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Contact Person:
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Equivalent to: JTS Extendible Implant, Stanmore Implants (K092138)

Orthopaedic Salvage System (OSS); Biomet (K002757) Global Modular Replacement System (GMRS); Howmedica (Stryker) (K023087); Exactec Inc All Poly Acetabular Cup (K963313) and the Repiphysis Limb Salvage System Wright Medical (K021489).

Device Description: The single use METS® Modular Total Femur is a standard modular system that is intended for the replacement of diseased or deficient bone in the femur. The system is intended for cemented use only and comprises titanium (Ti) components including a trochanter section, shaft. The trochanter trunnion is made to interchange with Stanmore Implants Worldwide Limited's, 28mm and 32mm Ø Cobalt Chrome femoral heads. The METS® Modular Total Femur is offered with an optional set of trochanters which are only to be used for hard tissue attachment using a plate and two screws, or Ti or cobalt chromium (CoCr) wire.
A range of shafts, femoral component (including axle, bushes and circlip), bumper and the SMILES knee (available in 3 types of arrangements and in a rotating or fixed configuration).

	The materials used in the manufacture of the systems include titanium (Ti), cobalt-chromium-molybdenum (CoCrMo) and ultra high molecular weight polyethylene (UHMWPE).
Intended Use:	The METS® Modular Total Femur is intended for the replacement of the total femoral bone.
Indications for Use:	Limb salvage procedures where radical resection and replacement of the bone is required Painful and disabled joint resulting from avascular necrosis osteoarthritis, rheumatoid arthritis or traumatic arthritis Correction of varus, valgus or post traumatic deformity Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement Ligament deficiencies Tumor resections Revision of previously failed total joint arthroplasty Trauma Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques METS® Modular Total Femur tibial and acetabular components are for cemented use only. METS® Modular Total Femur and their components are for single use only.
Performance Data: **(non-clinical and clinical)**	<u>Non Clinical Testing</u> The results of the non-clinical performance testing demonstrate that the device is safe and effective and substantially equivalent to the predicate devices. The Performance testing included: knee fatigue and wear test, disassembly force testing for the taper connections, ASTM F1800-07. <u>Clinical Performance Conclusions</u> Clinical evaluation was carried out based upon published papers and post market surveillance.
Substantial Equivalence:	The METS® Modular Total Femur is equivalent to the following predicate devices: the JTS Extendible Implant (K092138); the Biomet OSS (K002757); the Howmedica (Stryker) GMRS (K023087); the Exactec All Poly Acetabular Cup (K963313) and the Repiphysis Limb Salvage System (K021489). The determination of substantial equivalence is based on the similarity of the intended use, indications for use, design / technological characteristics, materials of composition, method of sterilization, performance data and clinical evaluation.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Stanmore Implants Worldwide, Limited
% Health Policy Associates, Incorporated
Ms. Nancy C. McDonald
Manager, Regulatory Affairs
690 Canton Street, Suite 302
Westwood, Massachusetts 02090

SEP 17 2012

Re: K121055
Trade/Device Name: METS® MODULAR TOTAL FEMUR
Regulation Number: 21 CFR 888.3350
Regulation Name: Hip joint metal/composite semi-constrained cemented prothesis
Regulatory Class: Class II
Product Code: JDI, KRO
Dated: August 17, 2012
Received: August 17, 2012

Dear Ms. McDonald:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

SECTION 4:
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K121055

Device Name: **METS® MODULAR TOTAL FEMUR.**

Indications for Use:
The METS® Modular Total Femur is intended for the replacement of the total femoral bone.

Limb salvage procedures where radical resection and replacement of the bone is required
Painful and disabled joint resulting from avascular necrosis osteoarthritis, rheumatoid arthritis or traumatic arthritis
Correction of varus, valgus or post traumatic deformity
Correction of revision of unsuccessful osteotomy, arthrodesis, or previous joint replacement
Ligament deficiencies
Tumor resections
Revision of previously failed total joint arthroplasty
Trauma
Treatment of non-unions, femoral neck and trochanteric fracture of the proximal femur with head involvement, unmanageable using other techniques

All of the METS® Modular Total Femur tibial and acetabular components are for cemented use only

All of the METS® Modular Total Femur and their components are for single use only

Prescription Use X AND/ OR Over-The-Counter Use _____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE

for

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K121055